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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,645	01/24/2002	Anne Gillian Welch	9013.31	8639
20792	7590	05/15/2008		
MYERS BIGEL SIBLEY & SAJOVEC			EXAMINER	
PO BOX 37428			BOESEN, AGNIESZKA	
RALEIGH, NC 27627				
			ART UNIT	PAPER NUMBER
			1648	
			MAIL DATE	DELIVERY MODE
			05/15/2008 PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/889,645

Applicant(s)

WELCH ET AL.

Examiner

Agnieszka Boesen

Art Unit

1648

Period for Reply -- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3, 6-16, 25, 28, 31, and 32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/C2)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

The Amendment filed January 24, 2008 in response to the Office Action of August 24, 2007 is acknowledged and has been entered. Claims 1, 3, 6-16, 25, 28, 31, and 32 are under examination in this Office Action.

Claim Rejections - 35 USC § 112

Rejection of claim 1 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement **is withdrawn** as discussed during the interview of December 5, 2007.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Rejection of claims 1, 3, 6-16, 25, 28, 31, and 32 under 35 U.S.C. 103(a) as being unpatentable over Ostreicher et al. (GB 2 045 828 A, 1980) in view of Nebe (WO 96/05846, IDS Paper No. 1) as evidenced by Encyclopedia Britannica (britannica.com/eb/article-9030299/diatomaceous-earth, access 10/5/2006) **is maintained**.

Applicant's arguments have been fully considered but were not found persuasive. Applicants argue that the submicron contaminants such as bacteria, viruses or pyrogens taught by Ostreicher are not the same or similar to prion agents; and that submicron contaminants discussed by Ostreicher would not be expected to simulate soluble prion protein in the presence of plasma proteins as provided by the present invention. Applicants argue that the present invention relates to completely removing prion agents from protein solutions, specifically blood

plasma products. In response to Applicant's arguments the Office points out that the present claims broadly recite removing infective prion from an aqueous liquid containing a natural product and Ostreicher teaches a method of removing submicron contaminants from an aqueous system such as biological fluids (see page 10, lines 47-57). Thus because Ostreicher teaches aqueous system and specifically removing submicron contaminants from biological fluids Ostreicher's teaching reads on the present claims. Additionally, the independent claim 1 does not recite removing the infective prion from plasma or from a protein solution. Claim 1 broadly recites removing prion from aqueous liquid. Present claim 12 recites that the aqueous solution is human plasma. However, since human plasma is an aqueous solution the skilled artisan would have been motivated to remove submicron contaminants such as infectious prion from human plasma.

Applicants submit that Nebe fails to cure the deficiencies of Ostreicher because Nebe uses brain tissue homogenate which is not a clarified solution in contrast to the clarified brain extract used in the present invention. In response to Applicant's arguments the Office notes that the limitations argued by the Applicant's are not recited in the present claims. The claims do not recite the clarified solution or a clarified brain extract. The present claims broadly recite an aqueous liquid containing a natural product.

Applicants argue that the present inventors found that the prion agent could be removed using a depth filter with a nominal pore size 30x greater than the final pre-filter which failed to remove prion infectivity in Nebe. In response to Applicant's arguments the Office notes that Nebe teaches that prion proteins can be removed using filters that provide retention from 2.0 to 0.2 microns. Table 1 in present application shows removal of prion protein with using filters that

provide retention of 0.6 - 1.5, 3.5 - 6.0, 0.6, and 2.0. Thus because Nebe suggest that one can remove prions using filters providing retention of ranges taught in the present application, that is 2.0 - 0.6 microns, the skilled artisan would have known at the time of the present invention that prion protein contaminants can be removed using a filter providing the retention taught by Nebe. Thus the present invention would have been obvious in view of the cited references as discussed above and as discussed on the record. Thus the present rejection is maintained.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnieszka Boesen whose telephone number is 571-272-8035. The examiner can normally be reached on 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Agnieszka Boesen, Ph.D./
Examiner, Art Unit 1648

/Stacy B Chen/
Primary Examiner, Art Unit 1648